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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,143	12/22/1998	JEAN-LUC IMLER	029395-005	3481

21839 7590 12/12/2005

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/218,143	IMLER ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20051107</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 67 has been amended to recite “essential adenoviral E1 gene” and “essential adenoviral E4 gene”. Applicant asserts that the amendment is supported throughout the specification, but does not point to any specific part of the original disclosure that provides such support, as is Applicant’s burden. See MPEP 714.02, last sentence of the third paragraph from the end and 2163.06 (I) last sentence.

Unlike claim 66, which requires that the deleted E1 and E4 sequences be essential for replication, claim 67 only requires that the “genes” deleted be “essential” without specifying what they are essential for. The original specification teaches that the E1, E2, and E4 regions as a whole are essential for replication (pages 2-3), but also teaches (page 3, lines 13-18) that some E4 genes/gene products are involved in processes other than replication. These E4 “genes” are essential to whatever function they perform. The original specification does not describe a genus of adenovirus where E1 and E4 “genes” that are “essential” for some unspecified process are deleted.

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This rejection would be overcome by limiting the E1 and E4 genes being deleted to genes that are essential for replication of the adenovirus.

Claim Rejections - 35 USC § 102

Claim 67 remains rejected under 35 U.S.C. 102(e) as being clearly anticipated by Gregory et al., 5,670,488 for the reasons of record set forth in the Office action of 7/6/05.

Claim 67 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Berkner (Curr. Top. Microbiol. Immunol. 158: 39-66, 1992) in view of Bridge et al. (Virol. 174: 345-353, 1990) as required by the Board in Paper No. 62 of Interference No. 105136 at page 20 for the reasons set forth by the Board in pages 17-19.

Applicant's arguments filed 11/7/05 have been fully considered but they are not persuasive. Applicant asserts that the amendment of claim 67 requires a limitation that is not taught in the prior art. However, the claim does not indicate what the deleted E1 or E4 gene is essential for. The E4 region comprises several different open reading frames (genes) encoding different proteins that are essential for the functions they provide during the adenoviral life cycle. Not all of these are essential for replication of an adenovirus, however the claim does not require that they be so.

Double Patenting

Claims 66-67 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 18, 20, 21, and 24-26 of U.S. Patent No. 6,133,028.

Claims 66-67 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 81 and 85 of copending Application No. 09/725,720.

Applicant's arguments filed 11/7/05 have been fully considered but they are not persuasive. Applicant indicates that terminal disclaimers had been filed to overcome these rejections. However, no such terminal disclaimers have been submitted.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

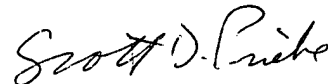
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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633